

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF CALIFORNIA

KARIN FUSSY,

Plaintiff,

v.

RTI SURGICAL,

Defendants.

Case No. 1:21-cv-01307-KES-CDB

FINDINGS AND RECOMMENDATIONS  
TO GRANT DEFENDANT'S MOTION TO  
DISMISS WITHOUT LEAVE TO AMEND

(Doc. 25)

ORDER STRIKING UNSIGNED MOTION  
FOR JUDGMENT

(Doc. 57)

ORDER VACATING SCHEDULING  
CONFERENCE

(Doc. 60)

**14-DAY DEADLINE**

Pending before the undersigned is the motion of Defendant RTI Surgical, Inc. ("Defendant"), to dismiss the first amended complaint of Plaintiff Karin Fussy ("Plaintiff"), filed on May 17, 2022.<sup>1</sup> (Doc. 25). Plaintiff, proceeding pro se, filed an opposition to the motion on May 31, 2022. (Doc. 28). Defendant filed a reply on June 10, 2022. (Doc. 29). The undersigned deems the motion suitable for resolution without hearing and oral argument. *See* E.D. Cal. Local Rule 230(g). For the reasons set forth below, the undersigned will recommend Defendant's motion to dismiss be granted without leave to amend.

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<sup>1</sup> On May 14, 2025, the assigned district judge referred the pending motion to dismiss to the undersigned for the preparation of findings and recommendations. (Doc. 56).

1 I. **BACKGROUND**<sup>2</sup>

2 Plaintiff, proceeding pro se, initiated this action with the filing of a complaint on March 17,  
3 2021, in the Kern County Superior Court, case number BCV-21-100589. (Doc. 1-1). Defendant  
4 removed the action to this Court on August 27, 2021. (Doc. 1). On September 2, 2021, Defendant  
5 filed a motion to dismiss the complaint. (Doc. 4). Plaintiff filed an untimely opposition on  
6 November 17, 2021. (Doc. 16). The Court granted the motion to dismiss on April 14, 2022, finding  
7 that Plaintiff had failed to cognizably allege any manufacturing defect claim, design defect claim,  
8 failure to warn claim, or negligence claim, and provided Plaintiff leave to amend. *See* (Doc. 22).  
9 On April 27, 2022, Plaintiff filed her first amended complaint. (Doc. 24).

10 According to the allegations in the first amended complaint, in 2012, Plaintiff underwent  
11 spine surgery to fix a damaged disk. (Doc. 24 at 6). During this operation, the operating surgeon  
12 used a “Pedicule Screw Rod and Screw Fixation System” (the “Pedicule System”) to stabilize  
13 Plaintiff’s spine. Plaintiff alleges that the Pedicle System used for her surgery was manufactured  
14 by Defendant. She alleges that the “surgery was excessive, the screws shifted and impeded on  
15 Plaintiff’s spine” causing significant pain as well as nerve damage, and that this was a “direct result  
16 of the [Pedicule System] manufactured by RTI Surgical.” Plaintiff alleges that her claim is that the  
17 Pedicle System “permanently crippled Plaintiff causing her to lose the ability to be employed.” *Id.*  
18 Plaintiff seeks \$10,000,00 in compensatory damages and \$20,000,000 in punitive damages. *Id.* at  
19 6-7.

20 Regarding manufacturing defects, Plaintiff states alleges that the “intention of the product  
21 was to stabilize the spine during fusion even though it was not FDA approved for the spine at the  
22 time of surgery” with the Pedicle System to then be removed. Plaintiff asserts that knowing “that  
23 this product causes neurological issues and nerve damage” hinders its usability, causing it to be  
24 liable under a manufacturing defect. Plaintiff includes an excerpt from a newspaper article,  
25 discussing pedicle screws generally, which she asserts is from the Washington Post, dated April  
26 18, 1995. *Id.* at 8.

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28 <sup>2</sup> References to Plaintiff’s first amended complaint are to the CM/ECF-assigned page  
number. (Doc. 24).

1           Regarding design defects, Plaintiff alleges that the FDA approval of the Pedicle System  
2 came “almost [five] full years after Plaintiff’s surgery,” and thus it was “not reasonably safe” at the  
3 time of the surgery. *Id.* at 9. The first amended complaint recites a quote from *Menges v. Depuy*  
4 *Motech, Inc.*, 62 F. Supp. 2d 817 (N.D. Ind. 1999), which purports to summarize the allegations by  
5 the plaintiff in that case, which appear somewhat similar to Plaintiff’s allegations here (i.e., that the  
6 pedicle screw device was not FDA-approved). She further alleges that, under a consumer  
7 expectation test, the typical consumer would not choose to use this product knowing of the potential  
8 risks. (Doc. 24 at 9). Plaintiff alleges that the Pedicle System, not having FDA approval for use  
9 on the spine, renders the product “‘not reasonably safe.’ The possible benefit does not outweigh  
10 the potential risk.” She asserts that, during her three follow-ups post-surgery (on March 28, 2012;  
11 May 16, 2012; and November 30, 2015), she complained of pain, leg weakness, slurred speech,  
12 and reduced stability. According to her allegations, the physician stated the Pedicle System could  
13 not cause such issues and sent Plaintiff for a neurological examination. Upon Plaintiff’s request  
14 for removal of the Pedicle System, the physician informed Plaintiff the product was intended to be  
15 permanent and insurance would not cover removal. Plaintiff alleges that the fact that the physician  
16 “was an owner in the company makes him an extension of the manufacturer and the deception  
17 creates an unsafe product.” She states that the Pedicle System “manufactured by [Defendant] were  
18 presented with the issues and potential dangers of their product and failed to warn the Plaintiff  
19 making [Defendant] liable under Design Defect.” *Id.* at 10.

20           Regarding failure to warn, Plaintiff asserts that the learned intermediary doctrine is rendered  
21 inapplicable here because “the physician was an owner in the company and therefore that makes  
22 him an extension of the company. Therefore, his lack of warning to the patient is valid.” Plaintiff  
23 alleges that the physician, in the operative report, states the “patient is aware that this procedure  
24 may not meet expectations” and warnings of the possibility of “neurological issues” or “symptoms  
25 being worse were not presented to the Plaintiff ... the original use was intended to be temporary”  
26 and, upon seeking removal, Plaintiff was “told that it was a permanent fixation not meant to be  
27 removed” and that the Pedicle System was not the issue. *Id.* at 11. Plaintiff alleges she was never  
28 informed that the Pedicle System was experimental, quoting a passage allegedly from a Washington

1 Post article dated April 18, 1995, concerning a survey where surgical patients reported they had not  
2 been told the “screws were experimental.” *Id.* She includes what appears to a screenshot of a  
3 portion of an article titled “Pedicule Screws for Spinal Fusion,” by Peter Ullrich, dated January 20,  
4 2004, stating that the “screws and rods ... may be safely removed” once no longer needed but “most  
5 surgeons do not recommend removal unless the pedicle screws cause discomfort for the patient  
6 (5% to 10% of cases).” *Id.* at 12.

7 Plaintiff alleges that Defendant had a duty to manufacture safe and effective medical  
8 devices, Plaintiff’s injuries are a direct result of their Pedicle System, and the “negligence of  
9 [Defendant’s] actions caused a breach of duty putting the Plaintiff in harms [sic] way.” *Id.* She  
10 alleges the treatment was needless and excessive and believes the “surgery was done as an  
11 experiment in order to be used as an example of the [Pedicule System’s] success” in order to obtain  
12 FDA approval. *Id.* at 12-13.

## 13 **II. GOVERNING AUTHORITY**

14 A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) tests a complaint’s  
15 sufficiency and asks a court to dismiss a plaintiff’s complaint for failing “to state a claim upon  
16 which relief can be granted.” Fed. R. Civ. P. 12(b)(6); *N. Star Int’l v. Ariz. Corp. Comm’n.*, 720  
17 F.2d 578, 581 (9th Cir. 1983) (citing *Peck v. Hoff*, 660 F.2d 371, 374 (8th Cir. 1981)). A complaint  
18 may be dismissed as a matter of law either for lack of a cognizable legal theory or the absence of  
19 sufficient facts alleged under a cognizable legal theory. *Balistreri v. Pacifica Police Dep’t*, 901  
20 F.2d 696, 699 (9th Cir. 1990) (citing *Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d 530, 533-  
21 34 (9th Cir. 1984)).

22 To survive a motion to dismiss under Rule 12(b)(6), a complaint must provide sufficient  
23 factual matter to state a claim to relief that is plausible on its face. *Ashcroft v. Iqbal*, 556 U.S. 662,  
24 678 (2009); *see* Fed. R. Civ. P. 8(a)(2) (a complaint must contain a short and plain statement of the  
25 claim showing that the pleader is entitled to relief). A complaint satisfies the plausibility  
26 requirement if it contains sufficient facts for the court to “draw [a] reasonable inference that the  
27 defendant is liable for the misconduct alleged.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555  
28 (2007).

When considering a Rule 12(b)(6) motion to dismiss for failure to state a claim, the court must accept as true all factual allegations put forth in the complaint and construe all facts and inferences in favor of the non-moving party. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007) (citations omitted); *Hebbe v. Pliler*, 627 F.3d 338, 340 (9th Cir. 2010). The complaint need not include “detailed factual allegations,” but must include “more than an unadorned, the-defendant-unlawfully-harmed-me accusation.” *Iqbal*, 556 U.S. at 678 (citations omitted). The Court is “not ‘required to accept as true allegations that contradict exhibits attached to the Complaint or matters properly subject to judicial notice, or allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences.’” *Seven Arts Filmed Entm’t, Ltd. v. Content Media Corp. PLC*, 733 F.3d 1251, 1254 (9th Cir. 2013) (quoting *Daniels-Hall v. Nat’l Educ. Ass’n*, 629 F.3d 992, 998 (9th Cir. 2010)). Further, while factual allegations are accepted as true, legal conclusions are not. *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555).

Finally, courts must construe pro se pleadings liberally and hold such pleadings to a less stringent standard than those drafted by attorneys. *Boag v. MacDougall*, 454 U.S. 364, 365 (1982) (per curiam); see *Hughes v. Rowe*, 449 U.S. 5, 9 (1980) (“It is settled law that the allegations of [a pro se litigant’s complaint] ‘however inartfully pleaded’ are held ‘to less stringent standards than formal pleadings drafted by lawyers . . .’” (quoting *Haines v. Kerner*, 404 U.S. 519, 520 (1972))). A court should dismiss a pro se complaint without leave to amend only if “it is absolutely clear that the deficiencies of the complaint could not be cured by amendment.” *Akhtar v. Mesa*, 698 F.3d 1202, 1212 (9th Cir. 2012).

### **III. DISCUSSION**

First, Plaintiff filed a “motion for judgment” on May 19, 2025, wherein she requests the Court to rule on the pending motion to dismiss. (Doc. 57). The Court will construe Plaintiff’s motion as, more properly, a motion to expedite. See *Castro v. United States*, 540 U.S. 375, 381–82 (2003) (explaining that courts may recharacterize a pro se motion to “create a better correspondence between the substance of a pro se motion’s claim and its underlying legal basis”). This Court does not have an expedited calendar. As of the date of this order, the undersigned presides over more than 460 civil cases in various states of litigation and the assigned district judge

1 presides over more than 800 civil cases. While the Court regrets the delays in the litigation of this  
2 action, they are unavoidable given the tremendous judicial resource emergency experienced  
3 throughout this District.

4 Further, Plaintiff's motion is unsigned. As the Court advised in both its Informational Order  
5 (Doc. 3-5 at 2; citing Local Rule 131 & Fed. R. Civ. P. 11(a)) and Order Striking Unsigned Pleading  
6 (Doc. 43 at 2), each document submitted for filing must include the original signature of the filing  
7 party. As a general rule, all documents submitted without the required signature(s) will be stricken  
8 from the record. Plaintiff has been cautioned of this twice before. (Doc. 21 at 1 n.1; Doc. 43 at 2).  
9 Thus, the Court will strike Plaintiff's motion for judgment. (Doc. 57). Plaintiff is again directed  
10 to refamiliarize herself with and adhere to the Local Rules of this Court; failure to comply with  
11 those rules or Court orders may result in the imposition of sanctions.

12 Second, Defendant states in its motion to dismiss that the Pedicle System at issue here was  
13 "cleared for marketing and sale in the U.S. by the [FDA] pursuant to the agency's 510(k) or  
14 'substantial equivalence' process." (Doc. 25 at 3). Plaintiff does not dispute this, except regarding  
15 the time of her surgery in 2012, and includes in her first amended complaint text that she asserts is  
16 from an "[a]nnouncement from the FDA published [January 24], 2017," stating that "pedicle  
17 screw systems became classified as a Class II/special controls device by the FDA" effective  
18 December 30, 2016. (Doc. 24 at 12; Doc. 28 at 2). As such, preemption is not at issue here. *See*  
19 *Hobus v. Howmedica Osteonics Corp.*, 699 F. Supp. 3d 1122, 1138 n.12 (D. Or. 2023), *aff'd*, No.  
20 23-3528, 2025 WL 25694 (9th Cir. Jan. 3, 2025); *see also Merancio v. Smith & Nephew, Inc.*, No.  
21 1:15-CV-00807-DAD-EPG, 2017 WL 2257124, at \*6 n.7 (E.D. Cal. May 23, 2017).

22 Turning to the motion to dismiss (Doc. 25), the undersigned will discuss each of Plaintiff's  
23 claim in turn below.

24 **A. Manufacturing Defect Claims**

25 Pursuant to California law, a "manufacturing or production defect is readily identifiable  
26 because a defective product is one that differs from the manufacturer's intended result or from other  
27 ostensibly identical units of the same product line. For example, when a product comes off the  
28 assembly line in a substandard condition it has incurred a manufacturing defect." *Barker v. Lull*

1 *Engineering Co.*, 20 Cal. 3d 413, 429 (1978). Such a claim provides that “a suitable design is in  
2 place, but that the manufacturing process has in some way deviated from that design.” *In re*  
3 *Coordinated Latex Glove Litigation*, 99 Cal. App. 4th 594, 613 (2002). “A plaintiff pursuing a  
4 manufacturing defect claim must identify/explain how the product either deviated from the  
5 manufacturer’s intended result/design or how the product deviated from other seemingly identical  
6 models; therefore, a bare allegation that the product had ‘a manufacturing defect’ is an insufficient  
7 legal conclusion.” *Zetz v. Boston Sci. Corp.*, 398 F. Supp. 3d 700, 707–08 (E.D. Cal. 2019) (citing  
8 *Lucas v. City of Visalia*, 726 F. Supp. 2d 1149, 1155 (E.D. Cal. 2010)).

9 In dismissing Plaintiff’s original complaint, the Court instructed Plaintiff that if she  
10 intended to assert a manufacturing defect claim, she would be required to advance “allegations  
11 identifying and explaining how the pedicle screws either deviated from defendant’s intended  
12 result/design or how the screws deviated from other identical products.” (Doc. 22 at 4). However,  
13 in the first amended complaint, Plaintiff again fails to set forth allegations supporting a  
14 manufacturing defect claim. Plaintiff does not provide how the Pedicle System either deviated  
15 from the Defendant’s intended result or design, nor how the Pedicle System deviated from other  
16 products. Plaintiff appears to concede in her opposition to Defendant’s motion that her allegations  
17 support a design defect rather than manufacturing defect, stating that the “manufacturer knew the  
18 screws were defective and continued to sell them ... Therefore, the product did ‘differ’ from  
19 [Defendant’s] intended design, the defect was in the design itself ...” (Doc. 28 at 4, 8).

20 Accordingly, Plaintiff again fails to adequately allege a manufacturing defect claim under  
21 California law in her first amended complaint.

## 22 **B. Design Defect Claims**

23 California law provides two separate tests for establishing that a product design is  
24 defective. “A product is defective in design if the benefits of the design do not outweigh the risk  
25 of danger inherent in the design (risk-benefit test), or if the product fails to perform as safely as an  
26 ordinary consumer would expect when used in an intended or reasonably foreseeable manner  
27 (consumer expectations test).” *Garrett v. Howmedica Osteonics Corp.*, 214 Cal. App. 4th 173,  
28 182 (2013) (citing *Barker*, 20 Cal. 3d at 418). “The two tests provide alternative means for a



1 plaintiff to prove design defect and do not serve as defenses to one another.” *McCabe v. Am.*  
2 *Hondo Motor Co., Inc.*, 100 Cal. App. 4th 1111, 1121 (2002).

3 However, California law precludes strict liability for design defects by manufacturers of  
4 prescription medical devices, including implanted devices such as the Pedicle System at issue  
5 here. *See Garrett*, 214 Cal. App. 4th at 182 (finding “an exemption from design defect strict  
6 products liability for all implanted medical devices that are available only through the services of  
7 a physician”). “[T]he appropriate test for determining a prescription [medical device]  
8 manufacturer’s liability for a design defect involves an application of the ordinary negligence  
9 standard.” Under that standard, “a manufacturer is liable for a design defect only if it failed to  
10 warn of a defect that it either knew or should have known existed.” *Id.* (citing *Brown v. Superior*  
11 *Court*, 44 Cal. 3d 1049, 1057 (1988)).

12 In dismissing Plaintiff’s original complaint, the Court instructed Plaintiff that if she  
13 intended to assert a design defect claim, she would be required to advance “allegations identifying  
14 what aspect of the pedicle screws’ design made them defective or how defendant failed to warn  
15 about said defect.” (Doc. 22 at 4-5). However, in the first amended complaint, Plaintiff again fails  
16 to set forth any assertions supporting a design defect claim. The case of *Menges v. Depuy Motech,*  
17 *Inc.*, cited by Plaintiff in her opposition, is inapplicable here as the *Menges* court applied Wisconsin  
18 law. 61 F. Supp. 2d 817, 823 n.2 (N.D. Ind. 1999). Here, under governing California law, strict  
19 liability is precluded on a design defect claim. Regarding the applicable ordinary negligence  
20 standard, Plaintiff does not provide how the Pedicle System’s design made it defective nor how  
21 Defendant failed to warn of any such defect, as further discussed below in subsections (C) and (D).

22 Accordingly, Plaintiff again fails to adequately allege a design defect claim under California  
23 law in her first amended complaint.

### 24 **C. Failure to Warn Claims**

25 Pursuant to California law, a failure-to-warn claim may be pled under either a theory of  
26 negligence or a theory of strict liability. *Hannan v. Boston Sci. Corp.*, No. 19-cv-08453-PJH, 2020  
27 WL 2128841, at \*6 (N.D. Cal. May 6, 2020). “A plausible claim for a failure to warn should  
28 include allegations that *inter alia* identify which danger was not warned against, explain that the



1 danger was substantial, and that the danger was known or reasonably knowable, or explain how  
2 any warning that was given was inadequate.” *Marroquin v. Pfizer, Inc.*, 367 F. Supp. 3d 1152,  
3 1161 (E.D. Cal. 2019) (citing *Lucas*, 726 F. Supp. 2d at 1156 n.1).

4 “California’s learned intermediary doctrine holds that a manufacturer of prescription drugs  
5 or medical devices satisfies its duty to warn when it provides adequate warnings to the prescribing  
6 physician, as opposed to the patient ... The learned intermediary doctrine applies to implanted  
7 medical devices ... and it covers failure to warn claims under both the strict liability theory and the  
8 negligence theory.” *Zetz*, 398 F. Supp. 3d at 706-707 (citations omitted); see *Motus v. Pfizer Inc.*  
9 (*Roerig Div.*), 358 F.3d 659, 661 (9th Cir. 2004) (“[Defendant] is obligated to warn doctors, not  
10 patients, of potential side-effects associated with its pharmaceutical products[.]”).

11 “The learned intermediary doctrine, as this rule is known, has been extended in California  
12 to implantable medical devices in addition to prescription drugs ... In the case of prescription drugs  
13 and implants, the physician stands in the shoes of the ‘ordinary user’ because it is through the  
14 physician that a patient learns of the properties and proper use of the drug or implant. Thus, the  
15 duty to warn in these cases runs to the physician, not the patient.” *Bigler-Engler v. Breg, Inc.*, 7  
16 Cal. App. 5th 276, 319, 213 (2017) (quotations omitted; citing *Valentine v. Baxter Healthcare*  
17 *Corp.*, 68 Cal. App. 4th 1467, 1483 (1999)). “In the case of medical prescriptions, if adequate  
18 warning of potential dangers of a drug has been given to doctors, there is no duty by the drug  
19 manufacturer to insure that the warning reaches the doctor’s patient for whom the drug is  
20 prescribed.” *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 65 (1973) (quotations omitted; citing  
21 *Love v. Wolf*, 226 Cal. App. 2d 378, 395 (1964)).

22 A plaintiff who brings a claim “based on a failure to warn must prove not only that no  
23 warning was provided or the warning was inadequate, but also that the inadequacy or absence of  
24 the warning caused the plaintiff’s injury.” *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1238  
25 (9th Cir. 2017).

26 In dismissing Plaintiff’s original complaint, the Court instructed Plaintiff that if she  
27 intended to assert a failure to warn claim, she would be required to advance allegations identifying  
28 “what danger she should have been warned against, how that danger was substantial, or in what

1 capacity defendant knew about that danger.” (Doc. 22 at 6-7). In the first amended complaint,  
2 Plaintiff again fails to allege that Defendant did not adequately warn the prescribing physician.  
3 Plaintiff once more provides sparse allegations that suggest that a physician prescribed the spine  
4 surgery Plaintiff received and also prescribed using Defendant’s Pedicle System to hold Plaintiff’s  
5 spine in place. (Doc. 1-1 at 11; Doc. 24 at 6). As the Court informed Plaintiff in its prior order  
6 granting Defendant’s motion to dismiss the initial complaint, Plaintiff must allege “(1) defendant  
7 did not warn plaintiff’s doctors of the risks associated with the pedicle screws or the warning was  
8 inadequate, and (2) that the inadequacy or absence of the warning caused plaintiff’s injuries.” (Doc.  
9 22 at 7; quotations and citations omitted).

10 Plaintiff pleads no such facts. Rather, she alleges that the physician who conducted the  
11 operation was an “owner” of Defendant and, therefore, an extension of the manufacturer,  
12 presumably then requiring Defendant to warn Plaintiff directly. Plaintiff provides no citations to  
13 any supporting authority for such a proposition and the Court cannot locate any. *See Kamlade v.*  
14 *LEO Pharma Inc.*, No. 1:21-CV-00522-DAD-EPG, 2022 WL 358429, at \*5 (E.D. Cal. Feb. 7,  
15 2022) (“Finally, even if a design defect claim was asserted, plaintiff has cited no cases holding that  
16 the learned intermediary doctrine does not apply to such claims.”); *see also Sidhu v. Bayer*  
17 *Healthcare Pharms. Inc.*, No. 22-CV-01603-BLF, 2022 WL 17170159, at \*4 (N.D. Cal. Nov. 22,  
18 2022) (collecting cases).

19 Accordingly, Plaintiff again fails to adequately allege a failure to warn claim under  
20 California law in her first amended complaint.

#### 21 **D. Negligence Claims**

22 Pursuant to California law, “under either a negligence or a strict liability theory of products  
23 liability, to recover from a manufacturer, a plaintiff must prove that a defect caused injury ... Under  
24 a negligence theory, a plaintiff must also prove an additional element, namely, that the defect in the  
25 product was due to negligence of the defendant.” *Higginbottom v. Dexcom, Inc.*, 744 F. Supp. 3d  
26 1058, 1083 (S.D. Cal. 2024), *motion to certify appeal denied*, No. 24-CV-0195-WQH-BLM, 2024  
27 WL 4547017 (S.D. Cal. Oct. 22, 2024) (citing *Merrill v. Navegar, Inc.*, 26 Cal. 4th 465, 479  
28 (2001)). “As with a general negligence claim, the plaintiff must also show breach of duty,

causation, and damages. Therefore, a product is not negligently designed so long as the manufacturer took reasonable precautions in an attempt to design a safe product or otherwise acted as a reasonably prudent manufacturer would have under the circumstances.” *Lin v. Solta Med., Inc.*, 760 F. Supp. 3d 926, 944 (N.D. Cal. 2024) (quotations omitted; citing *Howard v. Omni Hotels Mgmt. Corp.*, 203 Cal. App. 4th 403, 428 (2012) & *Barker*, 20 Cal. 3d at 434).

In the first amended complaint, Plaintiff again fails to advance allegations explaining how the product created the alleged danger. Plaintiff states that her “permanent nerve damage” was a direct result of the Pedicle System (Doc. 24 at 12), but Plaintiff fails to assert facts regarding how Defendant’s actions are connected to any purported defects in the product. Plaintiff’s only other contention is that the Pedicle System was not approved for spinal stabilization by the FDA at the time of the surgery. However, this alone does not support a negligence claim. *See Perez v. Nidek Co.*, 711 F.3d 1109, 1115 (9th Cir. 2013) (explaining that “‘off-label’ usage of medical devices ... is an accepted and necessary corollary of the FDA’s mission to regulate [in the area of medical devices] without directly interfering with the practice of medicine”) (citations omitted); *see also Carson v. Depuy Spine, Inc.*, 365 F. App’x 812, 815 (9th Cir. 2010) (“The [Food, Drug, and Cosmetics Act] expressly protects off-label use ... In addition, the Supreme Court has emphasized that off-label use by medical professionals is not merely legitimate but important in the practice of medicine.”) (citations omitted).

Accordingly, Plaintiff again fails to adequately allege a negligence claim under California law in her first amended complaint. *See Higginbottom*, 744 F. Supp. 3d at 1084 (finding that “Plaintiff fails to allege nonconclusory allegations identifying what aspect of the insulin pump’s design made it defective or how any such defect resulted from Tandem’s negligence.”)

In sum, even liberally construing the allegations in the first amended complaint, the undersigned finds Plaintiff fails to state a claim against Defendant upon which relief may properly be granted. The undersigned therefore will recommend the Court grant Defendant’s motion to dismiss.

#### **E. Punitive Damages**

“In California, punitive damages are available in any action for breach of a non-contractual

obligation—including products liability actions ... —where it is proven by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice[.]” *Hill v. Novartis Pharm. Corp.*, No. 1:06-CV-00939-AWI, 2012 WL 967577, at \*2 (E.D. Cal. Mar. 21, 2012) (citations omitted). California Civil Code § 3294, subdivision (c) states that: “(1) ‘Malice’ means conduct which is intended by the defendant to cause injury to the plaintiff or despicable conduct which is carried on by the defendant with a willful and conscious disregard of the rights or safety of others. (2) ‘Oppression’ means despicable conduct that subjects a person to cruel and unjust hardship in conscious disregard of that person’s rights. (3) ‘Fraud’ means an intentional misrepresentation, deceit, or concealment of a material fact known to the defendant with the intention on the part of the defendant of thereby depriving a person of property or legal rights or otherwise causing injury.” Cal. Civ. Code § 3294(c).

Plaintiff has failed to allege any facts establishing oppression, fraud, or malice. As Plaintiff fails to state a claim in her first amended complaint, it follows that her request for punitive damages based on those same assertions fails. *See Funke v. Sorin Grp. USA, Inc.*, 147 F. Supp. 3d 1017, 1028 (C.D. Cal. 2015) (dismissing punitive damages claim where claims of “design, manufacture, and warnings” related to medical device had been dismissed).

#### **F. Leave to Amend**

Rule 15 provides that “leave [to amend] shall be freely given when justice so requires.” Fed. R. Civ. P. 15(2). However, district courts are only required to grant leave to amend if a complaint can be saved. *Lopez v. Smith*, 203 F.3d 1122, 1129 (9th Cir. 2000). When a complaint cannot be cured by additional facts, leave to amend need not be provided. *Doe v. United States*, 58 F.3d 494, 397 (9th Cir. 1995).

Plaintiff has already been granted leave to amend. However, Plaintiff’s first amended complaint fails to correct the deficiencies set forth in the Court’s order dismissing her initial complaint. *See* (Doc. 22, discussed *supra*). Given the facts and circumstances of Plaintiff’s claims as recounted above, the undersigned finds that further leave to amend Plaintiff’s claims would be futile and, accordingly, recommends that Defendant’s motion to dismiss be granted without leave to amend. *See Ferdik v. Bonzelet*, 963 F.2d 1258, 1261 (9th Cir. 1992) (noting discretion to deny

leave to amend is particularly broad where court has afforded plaintiff one or more opportunities to amend his complaint); *see also Ismail v. Cnty. of Orange*, 693 Fed. Appx. 507, 511-12 (9th Cir. 2017) (“A pro se complaint may be dismissed with prejudice when ‘it is absolutely clear that the deficiencies of the complaint could not be cured by amendment.’”) (quoting *Rosati v. Igbinoso*, 791 F.3d 1037, 1039 (9th Cir. 2015)).

#### IV. CONCLUSION AND RECOMMENDATION

For the foregoing reasons, IT IS HEREBY ORDERED that:

1. Plaintiff’s motion for judgment (Doc. 57) is STRICKEN.
2. The scheduling conference set for September 23, 2025 (Doc. 60), is VACATED, to be reset as necessary following resolution of the instant motion to dismiss.

And the undersigned RECOMMENDS that:

1. Defendant’s motion to dismiss (Doc. 25) be GRANTED.
2. Plaintiff’s first amended complaint (Doc. 24) be DISMISSED without leave to amend.

These Findings and Recommendations will be submitted to the U.S. District Judge assigned to this case, pursuant to the provisions of 28 U.S.C. § 636(b)(1). **Within 14 days** after being served with a copy of these Findings and Recommendations, any party may file written objections with the Court. Local Rule 304(b). The document should be captioned, “Objections to Magistrate Judge’s Findings and Recommendations” and **shall not exceed 15 pages** without leave of Court and good cause shown. The Court will not consider exhibits attached to the Objections. To the extent any party wishes to refer to any exhibit(s), that party should reference the exhibit in the record by its CM/ECF document and page number, when possible, or otherwise reference the exhibit with specificity. Any pages filed in excess of the 15-page limitation may be disregarded by

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1 the District Judge when reviewing these Findings and Recommendations under 28 U.S.C. §  
2 636(b)(1)(C). A party's failure to file any objections within the specified time may result in the  
3 waiver of certain rights on appeal. *Wilkerson v. Wheeler*, 772 F.3d 834, 839 (9th Cir. 2014).

4 IT IS SO ORDERED.

5 Dated: August 5, 2025

  
UNITED STATES MAGISTRATE JUDGE